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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/629,007

07/29/2003

Edward B. Dakin

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09/28/2006

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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/629,007

Applicant(s)

DAKIN ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 55-60 is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-17, 19, 20, 24-30, 35-39, 41, 42 and 46-51 is/are rejected.
- 7) ☒ Claim(s) 7, 8, 18, 21-23, 31-34, 40, 43-45 and 52-54 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/26/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 20 is objected to because of the following informality: In line 4, an adjective is apparently missing after the first occurrence of "fastener." Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 9, 25, 27, and 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The tubular support is said to contact and extend between bone and a bone fragment, and third or internal fasteners are said to be attached from within a bone interior. That is, bone, bone fragments, and a bone interior are essentially and improperly claimed as structural parts of the invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless—

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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5. Claims 1-6, 9-17, 19, 20, 24-30, 35, 39, 41, 42, and 46-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Cole et al. (6,068,648). Cole et al. disclose, at least in figures 6, 9, 10, and 12A-12E and in col. 9, line 13-39 and col. 14, line 10 to col. 15, line 47; an orthopedic fixation or bone fracture reduction system and a method with the system for positioning fragments of a bone fracture with respect to each other to reduce the fracture, where the system and method include a length of flexible, inelastic cord (20), a first or internal fastener (79 or 30), a second fastener (94), and an axially rigid tubular support (150 or 326), where the tubular support includes a series of segments (151, 152), where one of the segments is threaded (151), where the tubular support is extendable between bone and bone fragments, where one (94) of the fasteners includes an opening and a lock (a crimp) for locking the cord, where one fastener (79) has a threaded portion, where one fastener (30) includes a toggle portion, where one of the fasteners includes a bone plate (32), where the system includes a third fastener (150 if 326 is considered the tubular support) and a tensioning instrument (800), where the tubular support (150) inherently causes tension in the cord when the cord contacts the tubular support, and where the method includes securing the cord to bone fragments to restrain separation of bone fragments and draw fracture surfaces toward each other.

Allowable Subject Matter

6. Claims 7, 8, 18, 21-23, 31-34, 40, 43-45, and 52-54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in

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independent form including all of the limitations of the base claim and any intervening claims.

7. Claims 36-38 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses an orthopedic system and method with the system including, inter alia, a length of flexible, inelastic cord, first and second fasteners, and an axially rigid tubular support, where the tubular support includes pharmaceuticals or antibiotics, where one of the fasteners includes a threaded bore and a lock that is a threaded member, where the system includes second, flexible inelastic cord and a third fastener or a plurality of internal fasteners attachable from within a bone interior, where the method includes the tubular support contacting and extending between first and second bone segments and where first and second bone fragments are distracted from one another by positioning of the tubular support, and where the method includes a plurality of internal fasteners and a plurality of axially rigid tubular supports.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

9. Claims 55-60 are allowed.

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10. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, a method for reducing a bone fracture, where the method includes, inter alia, attaching a flexible cord from within the bone interior to a first bone fragment, attaching an internal pulley bearing the cord to a second bone fragment, passing an end of the cord through an opening in a third bone fragment, and advancing first and second axially rigid tubular supports over the cord or advancing an axially rigid tubular support over the cord and tensioning the passed through the third bone fragment. Also, none of the prior art of record discloses a bone fracture reduction system including, inter alia, an internal fastener, a pair of flexible inelastic cords attached to the internal fastener, a pair of axially rigid tubular supports, and a pair of external fasteners.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rambert et al. (3,896,500) and Dunn et al. (4,790,850) teach orthopedic fixation systems.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-

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4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

September 22, 2006